
**मॉड्यूलर लोअर लिम्ब ऑर्थोटिक
घटकों के लिए विशिष्टि**

भाग 5 संयुक्त इकाई
अनुभाग 2 मानक घुटने

**Specification for Modular Lower
Limb Orthotic Components**

Part 5 Joint Unit
Section 2 Standard knee

ICS 11.040.40

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Artificial Limbs, Rehabilitation Appliances and Equipment for Persons with Disability, Sectional Committee and approval by the Medical Equipment and Hospital Planning Division Council.

The formulation of this part of the standard was taken up to facilitate the manufacturers and the users of orthotic standard knee joint which will enable the persons with disability in using a quality product.

Orthotic knee joint is used by the physically impaired persons [Knee Ankle Foot Orthosis (KAFOs), Hip-Knee-Ankle-Foot-Orthosis (HKAFOs), Knee orthosis (KOs)]. It supports the anatomical knee to control the mobility. This standard will help in rationalizing the quality and dimensions of the standard knee joint. The device is fixed as an aid to perform some of the normal functions of the knee.

The clause **12** call for an agreement between the purchaser and the supplier.

The composition of the Committee responsible for the formulation of this standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 Rules for rounding off numerical values (*revised*). The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

SPECIFICATION FOR MODULAR LOWER LIMB ORTHOTIC COMPONENTS

PART 5 JOINT UNIT

Section 2 Standard knee

1 SCOPE

This standard (Part 5/Sec 2) covers the requirements of joint unit standard knee for modular lower limb orthoses.

2 REFERENCE

The standards listed below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

<i>IS No.</i>	<i>Title</i>
1586 (Part 1) : 2012	Metallic materials-rockwell hardness test: Part 1 Test method (scales A, B, C, D, E, F, G, H, K, N, T) (<i>fourth revision</i>)
4431 : 1978	Specification for carbon manganese free-cutting steels
9550 : 2001	Bright steel bars — Specification (<i>first revision</i>)
9879 : 1998	Method for emission spectrometric analysis of austenitic and ferritic stainless steels point to plane technique (<i>first revision</i>)

3 TYPE

Joint standard knee is of only one type in two sizes shall be as given below:

- a) Type - I (Drop-Lock):
 - 1) Size 2, and
 - 2) Size 3.

4 SHAPE AND DIMENSIONS

4.1 The joint unit standard knee of all Type I shall be in two sizes (Size 2 and 3). The typical shape of joints shall be as given in Fig. 1A, 1B, 1C, 1D and 2A, 2B, 2C and 2D.

**Table 1 Dimensions of Joint Unit —
Standard Knee — Type I**

All dimensions in millimeters

SI No.	Dimension	Size 2	Size 3
(1)	(2)	(3)	(4)
i)	$L (\pm 0.5)$	38.57	44.30
ii)	$L_1 \pm 0.5$	42	47.50
iii)	$R \pm 0.25$	12	15
iv)	Dia, D	9	9
v)	M Thread	M6	M6
vi)	$W_1 (\pm 0.25)$	16.7	20.5
vii)	$W_2 (\pm 0.25)$	6.2	6.2
viii)	$W_3 (\pm 0.25)$	20	25
ix)	$W_4 (\pm 0.25)$	11	11
x)	$B (\pm 0.3)$	20	25
xi)	$DL\ 1^*$	21	26
xii)	$DL\ 2^*$	28	32
xiii)	$DL\ 3^*$	11.3	11.6
xiv)	$DL\ 4^*$	15.7	16.9
xv)	Knee Flexion Range	130°	130°

*DL1 — Drop Lock Inner Length, DL2 — Drop Lock Outer Length,

*DL3 — Drop Lock Inner Width, DL4 — Drop Lock Outer Width

4.2 Overall Dimensions

The overall dimensions of the joint unit shall be as given in Fig. 1A, 1B, 1C, 1D and 2A, 2B, 2C and 2D.

5 FEATURES

5.1 Universal Design

One piece shall fit any side (left, right, inside and outside).

5.2 The range of motion (knee flexion) of joint unit-standard knee shall be 130 degree, first in its class leading to enhanced functional abilities.

5.3 Four side closed slot for better strength and security of the uprights, and its easily sliding in slots for the uprights

6 MATERIAL

6.1 The male and female parts of the joint unit shall be manufactured from corrosion resistant stainless steel conforming to the following chemical composition:

Carbon percent	0.08 <i>Max.</i>
Manganese percent	2.00 <i>Max.</i>
Phosphorus percent	0.045 <i>Max.</i>
Sulfur percent	0.030 <i>Max.</i>
Silicon percent	0.75 <i>Max.</i>
Chromium percent	16.00 - 18.00
Nickel percent	10.00 - 14.00
Molybdenum percent	2.00 - 3.00
Nitrogen percent	0.10 <i>Max.</i>
Iron percentage	Balance

6.2 The screw shall be manufactured from cold rolled bright steel annealed bars conforming to IS 9550 : 2001 'Bright steel bars — Specification (*first revision*)'.

6.3 The nut shall be made from carbon steel conforming to designation 25C12 S14 or 40C15 S12 or 40C10 S18 of IS 4431: 1978 'Specification for carbon manganese free-cutting steels'.

7 WORKMANSHIP AND FINISH

The male and female parts of joint shall be accurately machined and the joints faces shall be finished clean and free from tool marks. Fabrication by welding or brazing shall not be allowed. The outside surfaces of the joint shall be free from casting defects. All sharp edges and corners shall be rounded. The components shall be free from surface flaws and cracks.

8 HEAT TREATMENT

The male and female parts of the joint unit and the nut shall be solution annealed to 145 BHN (86 HRB).

9 TESTS

9.1 Chemical Test

The chemical composition of the test samples shall conform to requirements specified in **5.1** when testing in accordance with IS 9879 : 1998 'Method for emission spectrometric analysis of austenitic and ferritic stainless steels point to plane technique (*first revision*)'.

9.2 Mechanical Test

Mechanical test for load test and hardness test shall be carried out in accordance with IS 1586 (Part 1) : 2012.

9.2.1 Load Test

<i>Size</i>	<i>Minimum load</i>
2	75 kg
3	150 kg

10 MARKING

10.1 The product shall be marked with the manufacturer's name, initials or recognized trade mark and with proper identification of the type, size and materials.

10.2 BIS Certificate Marking

The standard knee may also be marked with the Standard Mark.

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations made there under. The details of the conditions under which the licence for use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

11 SAMPLING

A sampling scheme and criteria for acceptance shall be as agreed to between the purchaser and the manufacturer. However, a recommended scheme is given below.

11.1 Lot

All the sets of knee joints of the same type shall be grouped together to constitute a lot. Each lot shall be tested for the requirements of this specification.

11.2 Each set of knee joint with lock for orthosis shall be examined for shape and dimensions (**3**) and workmanship and finish (**6**). All those sets which fail in one or more of the above requirements shall be rejected and only the satisfactory sets of joints shall be accepted.

12 PACKING

The joint shall be packed in polyethylene bags. They may also be packed as agreed to between the manufacturer and the purchaser.

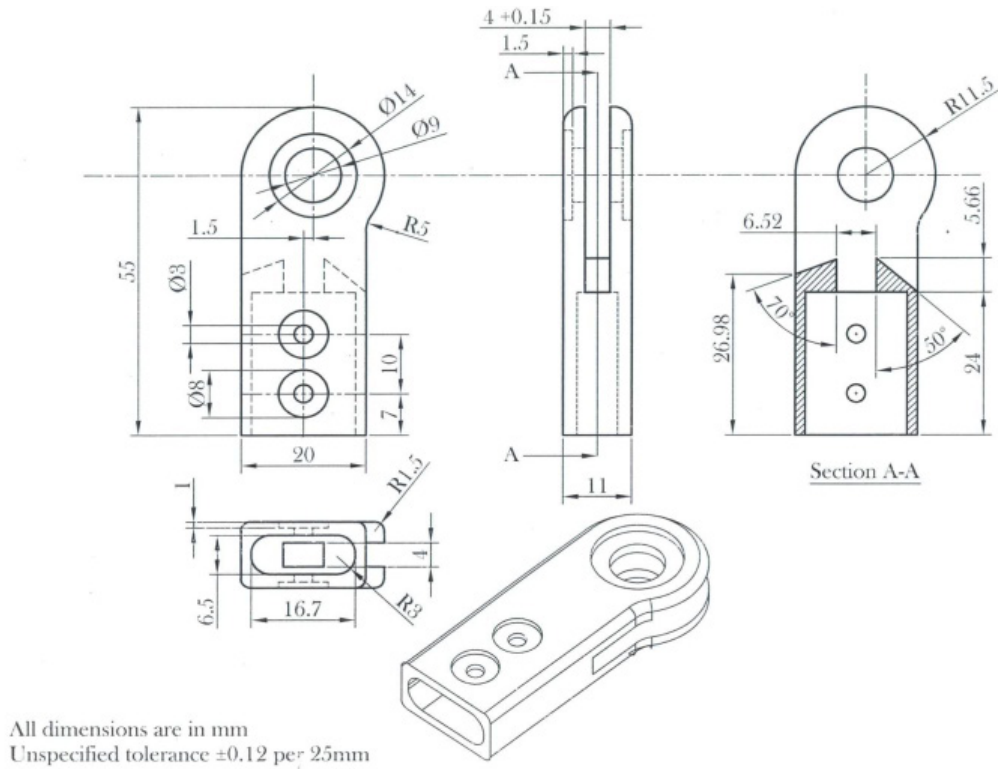


FIG. 1A JOINT UNIT — STANDARD KNEE (PART 1) — SIZE 2

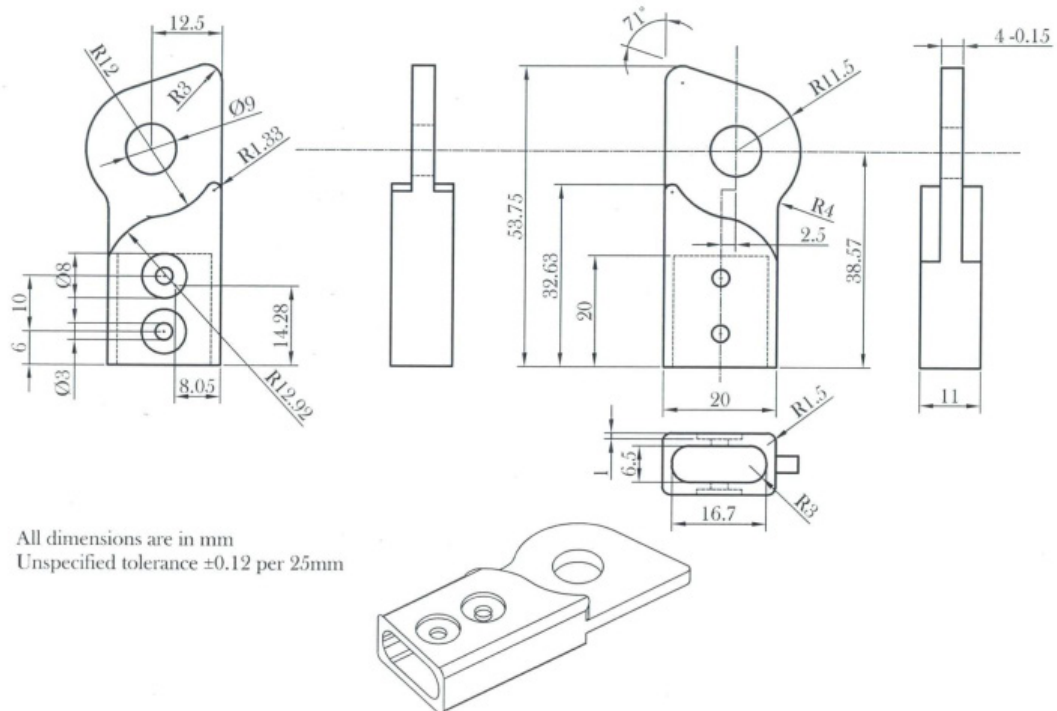
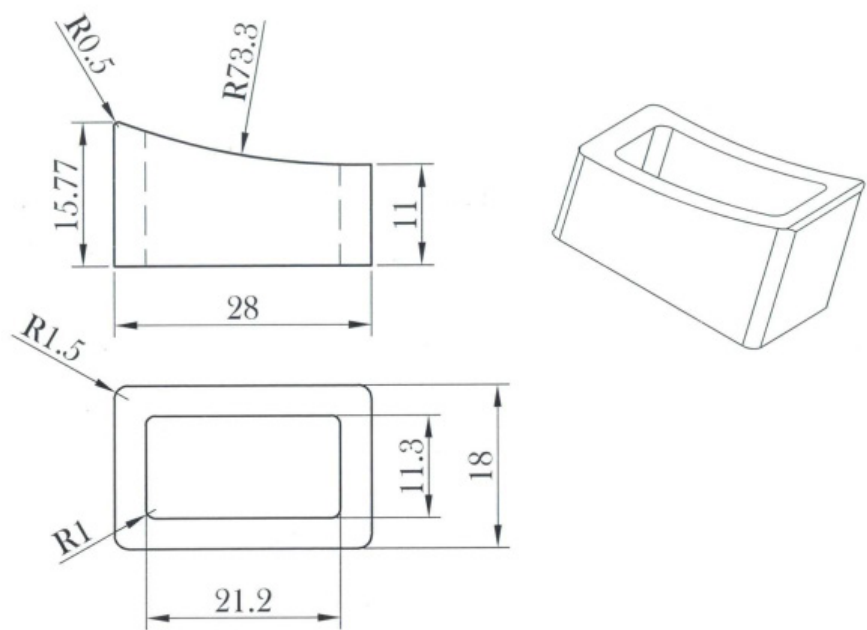


FIG. 1B JOINT UNIT — STANDARD KNEE (PART 2) — SIZE 2



All dimensions are in mm
Tolerance ± 0.12 per 25mm

FIG. 1C JOINT UNIT — STANDARD KNEE (PART 3) — SIZE 2

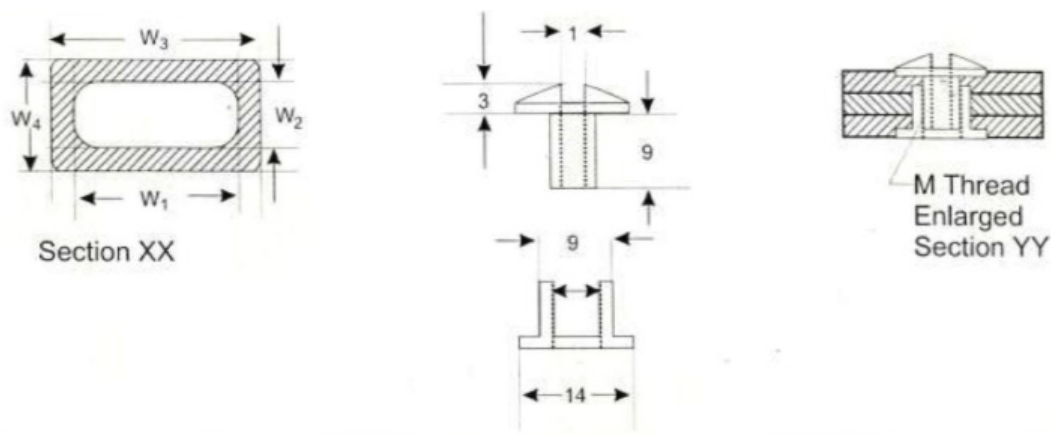


FIG. 1D JOINT UNIT — STANDARD KNEE (PART 4) — SIZE 2

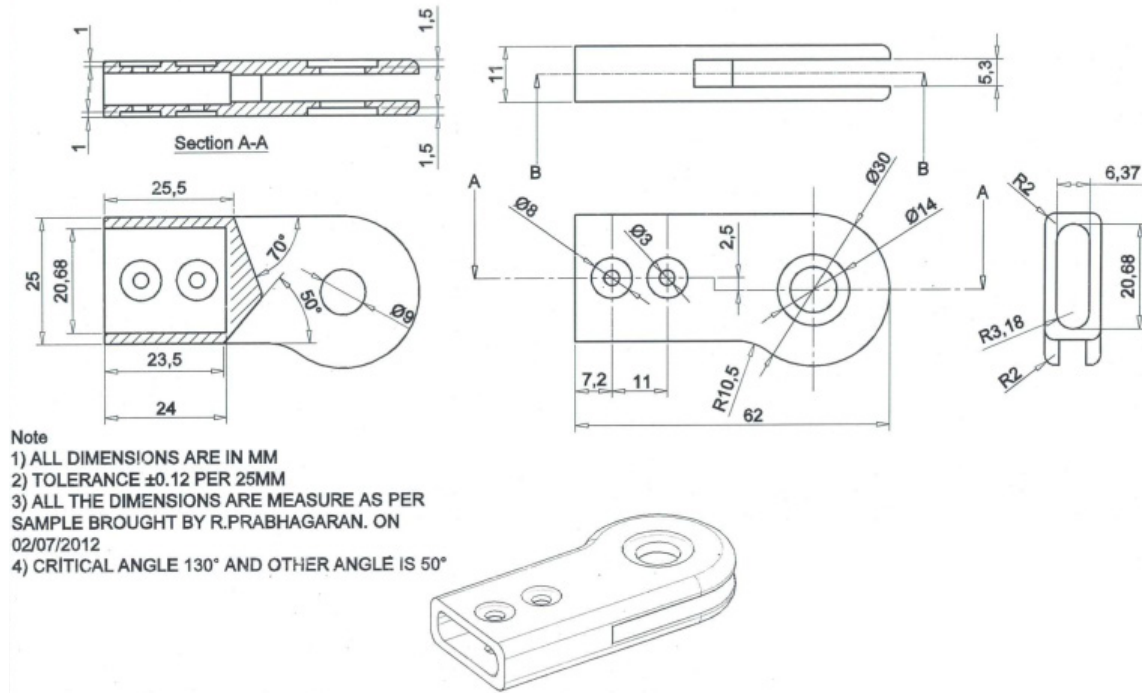


FIG. 2A JOINT UNIT — STANDARD KNEE (PART 1) — SIZE 3

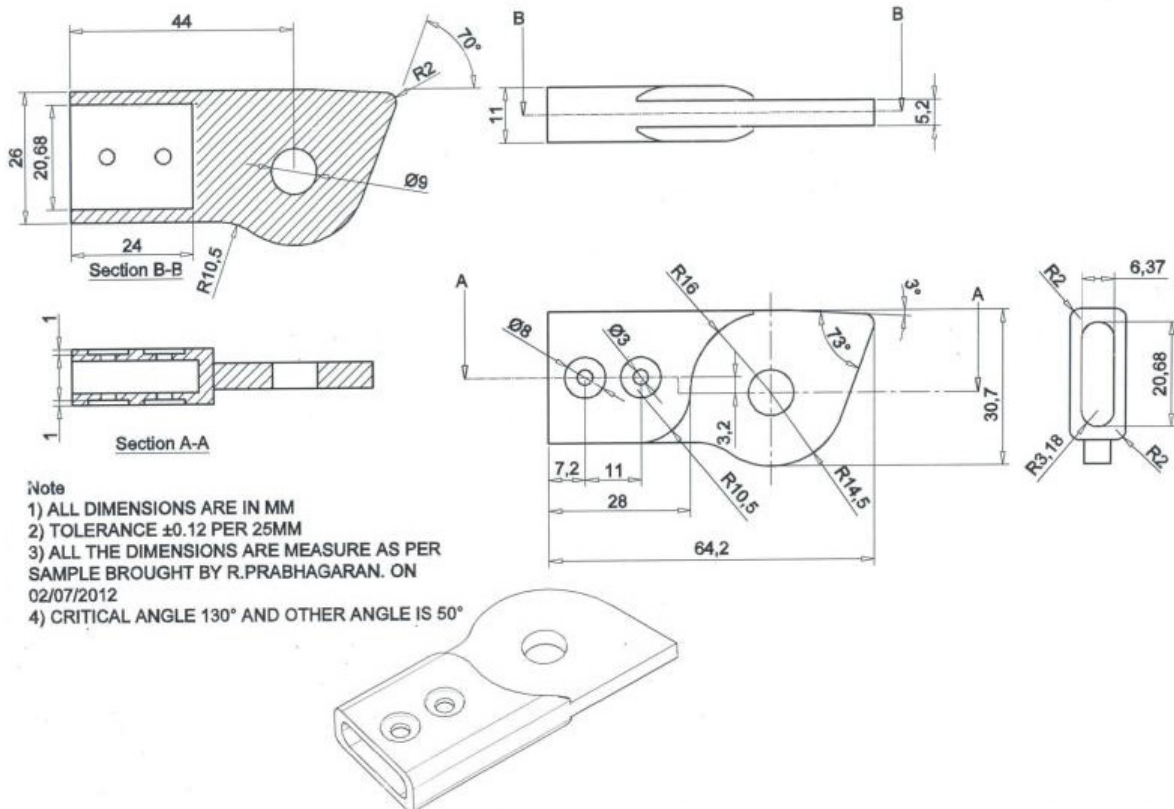


FIG. 2B JOINT UNIT — STANDARD KNEE (PART 2) — SIZE 3

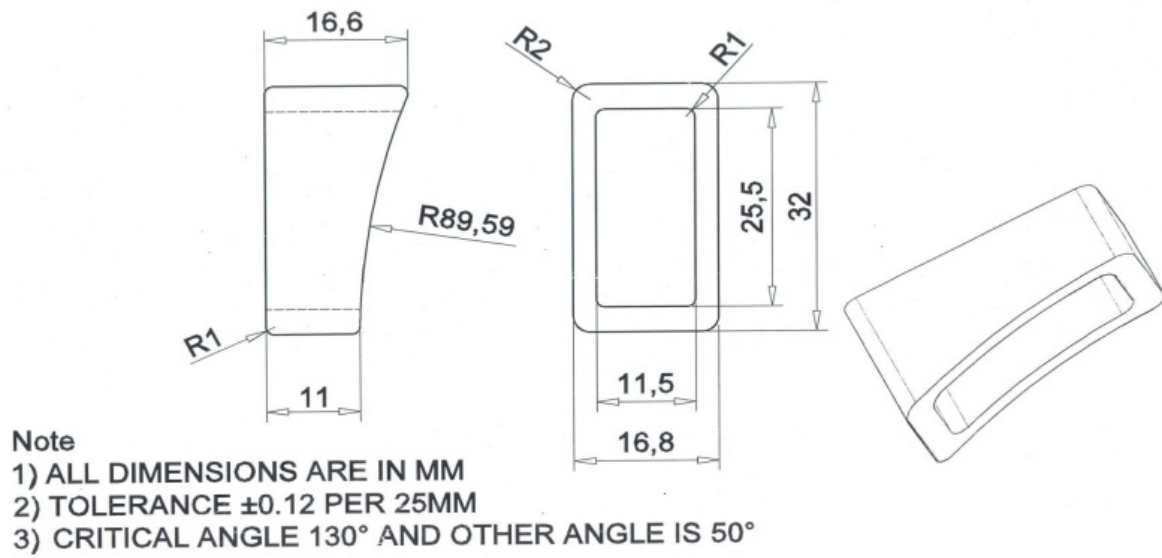


FIG. 2C JOINT UNIT — STANDARD KNEE (PART 3) — SIZE 3

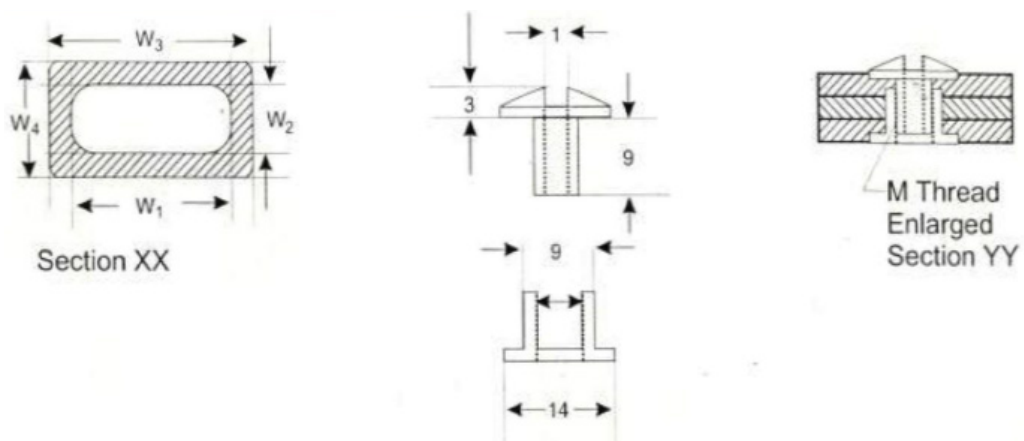


FIG. 2D JOINT UNIT — STANDARD KNEE (PART 4) — SIZE 3

ANNEX A*(Foreword)***COMMITTEE COMPOSITION**

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